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(54) **HEART VALVE ANNULOPLASTY
PROSTHESIS SEWING CUFFS AND
METHODS OF MAKING SAME**

USPC 623/2.1, 2.36, 2.37, 2.38, 2.39, 2.4,
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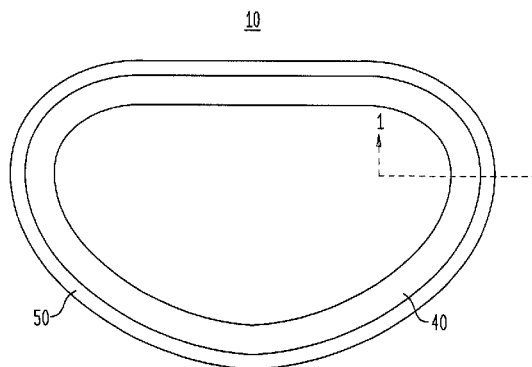
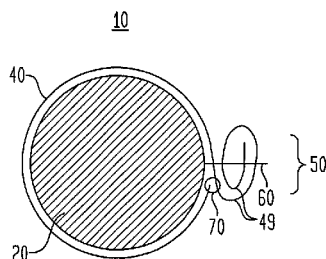
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(57) **ABSTRACT**

An annuloplasty prosthesis for a heart valve has a sewing cuff
added to the conventional structure. The sewing cuff is pref-
erably an extension of the fabric cover that is provided around
the core of the prosthesis. The sewing cuff preferably extends
radially outwardly from cross sections of the remainder of the
prosthesis. Methods of making such a sewing cuff are also
disclosed.

11 Claims, 5 Drawing Sheets



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FIG. 1

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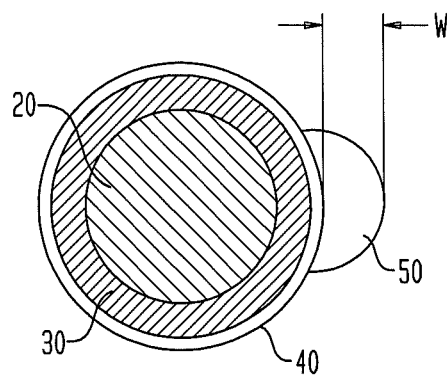


FIG. 2a



FIG. 2b

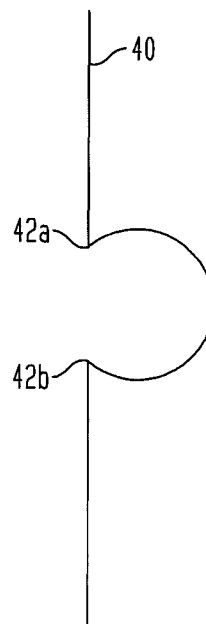


FIG. 2c

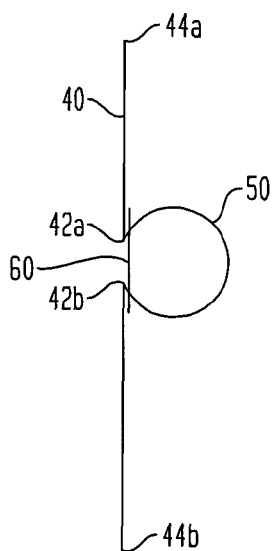


FIG. 2d

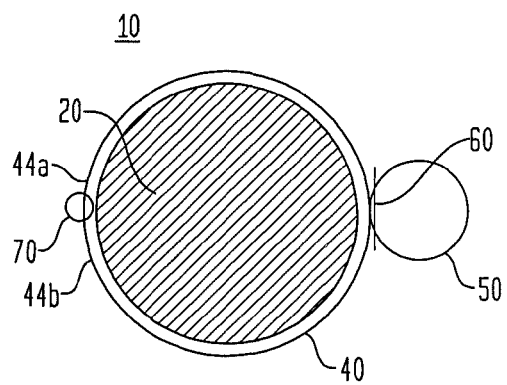


FIG. 3a

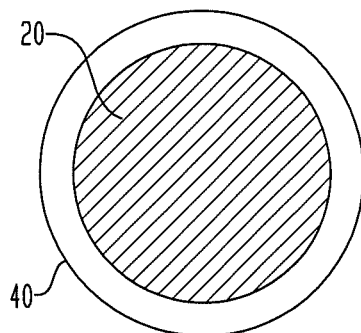


FIG. 3b

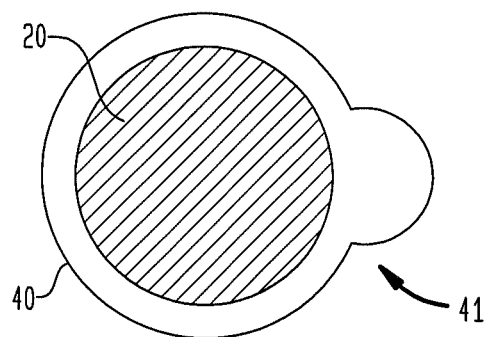


FIG. 3c

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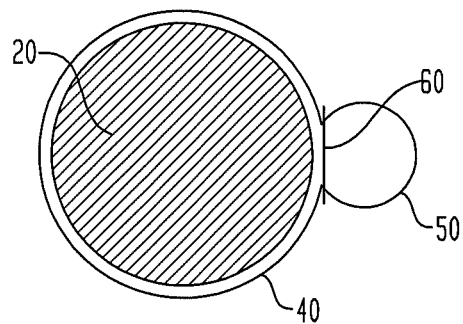


FIG. 4

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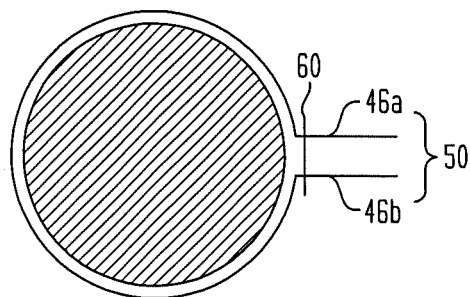


FIG. 5

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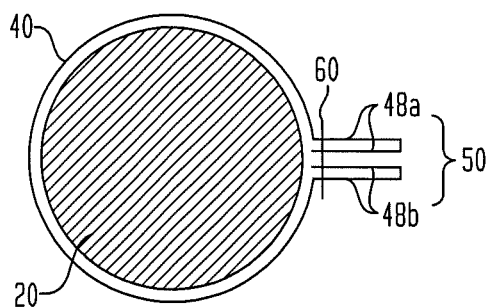


FIG. 6

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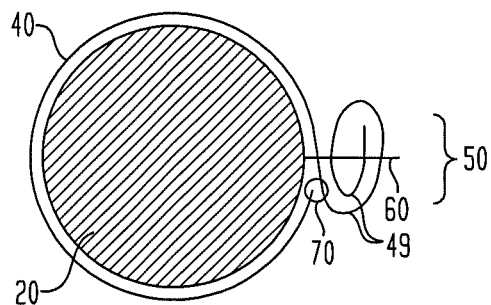
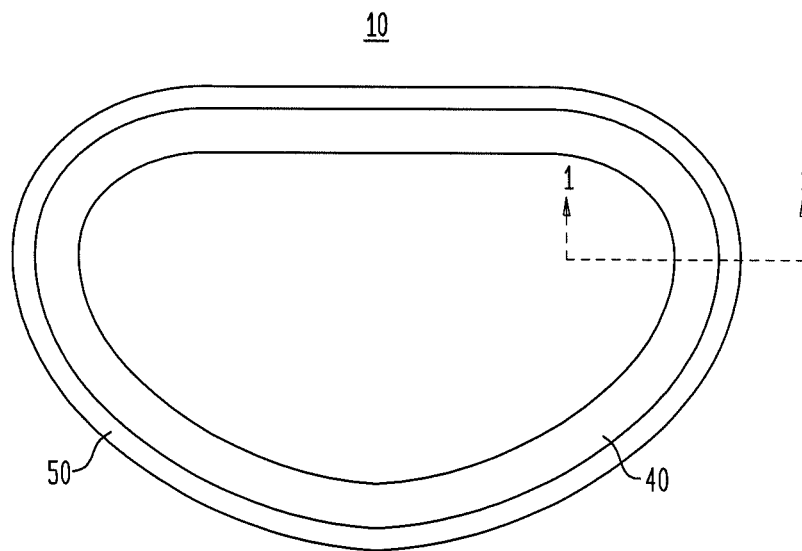


FIG. 7



1

HEART VALVE ANNULOPLASTY PROSTHESIS SEWING CUFFS AND METHODS OF MAKING SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 11/126,432, filed May 10, 2005, which claims the benefit of U.S. provisional patent application No. 60/571,437, filed May 14, 2004, all of which are hereby incorporated by reference herein in their entirety.

BACKGROUND OF THE INVENTION

Annuloplasty prostheses for heart valves are well known as is shown, for example, by Alfieri et al. U.S. patent application publication U.S. 2002/0173844 A1 and Bolling et al. U.S. patent application publication U.S. 2003/0093148 A1. Such prostheses may be complete rings (e.g., as in the above-mentioned Alfieri et al. and Bolling et al. references), or they may be less than complete rings (e.g., as in Carpentier U.S. Pat. No. 3,656,185). The term "annuloplasty" is used herein to refer to both of these types of prostheses (i.e., both complete rings and less than completely annular structures (e.g., generally C-shaped structures)).

Typical annuloplasty prostheses include a core member surrounded by a soft fabric cover. The core member is often substantially rigid or at least semi-rigid and not penetrable by a suture needle and suture material. The fabric cover may be designed to cushion the prosthesis, and possibly also to promote tissue in-growth into the prosthesis to help integrate the prosthesis into the patient's body. It is often desired to secure the prosthesis in the patient by passing one or more suture needles and suture material through the fabric cover and adjacent tissue. Tightness and/or thinness of the fabric cover may make this difficult to do. Even if the surgeon is successful in getting proper engagement, the amount of fabric caught may be less than would be desirable for good tissue healing and over-growth.

BRIEF SUMMARY OF THE INVENTION

To facilitate suturing an annuloplasty prosthesis into a patient, a sewing cuff is added to the prosthesis in accordance with the invention. Such a sewing cuff is preferably an extension of the fabric cover that is provided around the core of the prosthesis. The sewing cuff preferably extends radially outwardly from cross sections of the core and the remainder of the fabric cover. Stitching may be used to stabilize the extension. The extension may be one-piece with the fabric cover. For example, a medial portion of the cover fabric may be used to form the extension. As another example, a free edge portion of the fabric used for the cover may be used to provide the extension. The free edge portion may be folded to increase the bulk of the extension. Two free edge portions of the fabric used for the cover may be used together to form the extension. Again, folding may be used to increase the bulk of the extension.

The invention also includes various methods of making sewing cuffs such as those summarized in the preceding paragraph.

Further features of the invention, its nature and various advantages, will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a simplified cross sectional view of an illustrative embodiment of an annuloplasty prosthesis for a heart valve in accordance with the invention. FIG. 1 may be taken as shown at 1-1 in FIG. 7.

FIG. 2a is a simplified cross sectional view of an illustrative embodiment of a component that can be used in making a prosthesis like that shown in FIG. 1 in accordance with the invention.

FIG. 2b is similar to FIG. 2a, but shows a later stage in handling the component in accordance with the invention.

FIG. 2c is again similar to FIGS. 2a and 2b, but shows a still later stage in accordance with the invention.

FIG. 2d is generally similar to FIG. 1, but shows an end result from the progression of FIGS. 2a-2c in accordance with the invention.

FIGS. 3a-3c are each generally similar to FIG. 1, but show a progression in an alternative approach to making a prosthesis in accordance with the invention.

FIG. 4 is again generally similar to FIG. 1, but shows an alternative construction of a prosthesis in accordance with the invention.

FIG. 5 is once again generally similar to FIG. 1, but shows another alternative construction of a prosthesis in accordance with the invention.

FIG. 6 is again generally similar to FIG. 1, but shows still another alternative construction of a prosthesis in accordance with the invention.

FIG. 7 is a simplified plan view of an illustrative embodiment of a prosthesis in accordance with the invention.

DETAILED DESCRIPTION

The annuloplasty prosthesis 10 cross section shown in FIG. 1 includes core member 20, a layer 30 of an elastomeric material surrounding core 20, and fabric cover 40 surrounding elements 20 and 30. FIG. 1 also shows what may be described as a mini-sewing-cuff 50 extending radially outwardly from the other elements at one angular location or region around the circumference of the cross section. For completeness FIG. 7 shows a plan view of an entire illustrative annuloplasty prosthesis 10 in accordance with the invention and which can have a cross section as shown in FIG. 1 (or as in other FIGS. subsequent to FIG. 1). Although FIG. 7 shows the cross section taken at one particular location, substantially the same cross section may be found at other (or even all) locations annularly around prosthesis 10. Also, although FIG. 7 shows a prosthesis 10 that is a complete, unbroken, generally D-shaped annulus, prosthesis 10 could have other shapes, and could alternatively be only a portion of an annulus (e.g., it could be C-shaped rather than D-shaped). Still another point to be made is that although FIG. 7 shows sewing cuff 50 extending around the outside of prosthesis 10, sewing cuff 50 could alternatively be at any other location around cross sections of the prosthesis.

FIG. 7 is provided to make the point that, although most of the other FIGS. herein are of cross sections, these other FIGS. are representative cross sections of structures that extend longitudinally (e.g., out of the plane of the paper on which the cross sections are drawn).

Typical materials for the various components of prosthesis 10 will be mentioned later in this specification. For the moment it will be sufficient to point out that elastomeric layer 30 is optional and may be omitted in some embodiments of the invention. Fabric cover 40 would then be directly over core 20. The FIGS. subsequent to FIG. 1 show generalized

cores **20**, which can be either like core **20** in FIG. **1** or a composite of elements such as **20** and **30** in FIG. **1**.

Sewing cuff **50** can be formed on prosthesis **10** in any of a number of different ways. Some examples are shown in subsequent FIGS. and described below.

In the illustrative embodiment shown in FIGS. **2a-2d**, a medial (or more generally an interior) portion of fabric **40** is gradually pinched together as shown progressively in FIGS. **2a-2c** until two interior creases **42a** and **42b** are formed and brought together (FIG. **2c**). A fine suture **60** is then used to sew the two creases **42** together to create sewing cuff **50**. After the sewing cuff has been sewn together, the two free ends (edges) **44a** and **44b** of fabric **40** are wrapped around prosthesis core **20** and stitched together as shown at **70** in FIG. **2d**. Fabric **40** is pulled tightly together during stitching **70** so that it will securely and firmly wrap around prosthesis core **20**.

In the alternative embodiment illustrated by FIGS. **3a-3c**, fabric cover **40** is first wrapped loosely around prosthesis core **20**. A portion of the fabric annulus is gradually squeezed or pinched together as shown at **41** in FIG. **3b**. This eventually produces a sewing cuff. Depending on the width of the cuff required, the amount of fabric **40** squeezed or pinched together to create the cuff can vary. Suture **60** is added to hold sewing cuff **50** together as shown in FIG. **3c** to complete the process.

In the further alternative embodiment shown in FIG. **4**, sewing cuff **50** is created by squeezing together two otherwise free edges **46a** and **46b** of fabric **40** after the fabric has been wrapped around prosthesis core **20**. A fine suture **60** can then be used to stitch the two single-layers fabric edges together (and around core **20**) to form the sewing cuff. The width (radial outward projection) of the cuff (dimension **W** in FIG. **1**) can be determined by adjusting the amount of excess fabric **40** used to wrap around the core. More than just the single stitch line **60** can be used to hold edges **46a** and **46b** together in sewing cuff **50**.

In the still further alternative embodiment shown in FIG. **5**, fabric **40** is loosely wrapped around prosthesis core **20** with both edges **48a** and **48b** free. Free edges **48** are then folded over on themselves so that each free edge becomes double-layered. The two double-layered free edges are then squeezed together, and a fine suture **60** is used to stitch the fabric together to form sewing cuff **50**. A sewing cuff created in this way can be thicker (bulkier) and provide more cushioning. Free edges **48** can also be folded over multiple times to create a triple- or other multiple-layered cuff **50**.

In the further illustrative embodiment shown in FIG. **6**, sewing cuff **50** is first formed by folding a free edge portion of fabric **40** several times as shown at **49** to get the thickness desired. This is then stitched together with suture **60** so that the sewing cuff is stabilized and remains intact with the desired shape. The remaining free edge of fabric **40** is used to wrap around prosthesis core **20** and then stitched to the sewing cuff as shown at **70**. Fabric **40** will wrap around ring core **20** securely and firmly when the process is completed.

Sewing cuff **50** may measure from about 0.25 mm to about 5.0 mm in width (see dimension **W** in FIG. **1** or the comparable unreferenced dimension in any of the other FIGS.). The sewing cuff may be created from a soft fabric such as polyester, PTFE, or the like, and may be the same as (or even one piece with) fabric cover **40**. Sewing cuff **50** allows the surgeon to place sutures easily, and also provides substantially more fabric for tissue in-growth purposes. More sewing fabric also allows for a better cushion between the heart valve annulus and the prosthesis. As has been said, sewing cuff **50** can also be used with a prosthesis core that is first covered by a soft elastomer **30**, such as silicone or the like, before it is covered

by a fabric **40** with cuff **50**. The sewing cuff can also be used on just prosthesis core **20** itself without any intermediate elastomer covering **30**. Prosthesis core **20** can be made from any suitable material, such as stainless steel, titanium, ceramic, elgiloy, shape-memory alloy, and/or polymeric material.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, although the FIGS. herein show prostheses having cores **20** that are round in cross section, it will be appreciated that other core cross sectional shapes can be used instead if desired.

The invention claimed is:

1. An annuloplasty prosthesis for a heart valve comprising: an annular core having an outer surface;

a fabric having a first free end, a second free end, an inner surface on a first side of the fabric, an outer surface on a second side of the fabric opposite the first side, a first portion wrapped around the outer surface of the annular core so that the first side of the first portion faces toward the annular core and the second side of the first portion faces away from the annular core, and an end portion extending a distance from the first free end, the end portion being folded over on itself at least once against the second side of the fabric to form a sewing cuff having a folded portion extending radially outward from the annular core, the second free end being connected to the first side of the fabric so that the second free end is spaced from the first free end and so that the folded portion and the second free end are positioned on opposite sides of the fabric; and

a polymer layer arranged at least partially around the outer surface of the annular core and disposed between the annular core and the first portion of the fabric.

2. The annuloplasty prosthesis according to claim **1**, wherein the polymer layer comprises an elastomer.

3. The annuloplasty prosthesis according to claim **1**, wherein the polymer layer comprises silicon.

4. The annuloplasty prosthesis according to claim **1**, wherein the sewing cuff has an annular shape.

5. The annuloplasty prosthesis according to claim **1**, further comprising at least one suture disposed adjacent the outer surface of the annular core and attaching the sewing cuff to the first portion of the fabric.

6. The annuloplasty prosthesis according to claim **1**, wherein the end portion is folded over on itself multiple times.

7. The annuloplasty prosthesis according to claim **6**, further comprising at least one suture extending through the end portion of the fabric to maintain the end portion in a folded condition.

8. The annuloplasty prosthesis according to claim **1**, wherein the first portion of the fabric and the sewing cuff together are a one-piece structure.

9. The annuloplasty prosthesis according to claim **1**, wherein a first continuous segment of the fabric extends from the second free end and is wrapped around the outer surface of the core.

10. An annuloplasty prosthesis for a heart valve comprising:

an annular core having an outer surface;

a fabric having an inner surface on a first side of the fabric, an outer surface on a second side of the fabric opposite the first side, and first and second free ends, the fabric being wrapped around the outer surface of the annular core so that the first side of a first portion of the fabric faces toward the annular core and the second side of the

first portion of the fabric faces away from the annular core, the fabric extending from the second free end at least one complete revolution around the annular core to a connection point spaced from the first free end, the entirety of the first portion of the fabric between the 5 second free end and the connection point being firmly wrapped around the outer surface of the annular core, the fabric being folded over itself at least once against the second side of the fabric between the connection point and the first free end to form a sewing cuff having a 10 folded portion extending radially outward from the annular core, the second free end being connected to the fabric at the connection point so that the second free end is spaced from the first free end and so that the folded portion and the second free end are positioned on oppo- 15 site sides of the fabric; and

a polymer layer arranged at least partially around the outer surface of the annular core and disposed between the annular core and the first portion of the fabric.

11. The annuloplasty prosthesis according to claim **10**, 20 wherein the first portion of the fabric and the cuff together are a one-piece structure.

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